

**METHOD FOR REDUCING PRESSURE DAMAGE TO SKIN  
OF A PERSON, AND CORRESPONDING SKIN PROTECTIVE DEVICES**

**Field of the Invention**

The present invention relates to the field of health care, and in particular, to a method and corresponding skin protective devices for reducing pressure damage to skin of a person, particularly for a  
5 bedridden person.

**Background of the Invention**

Decubitus ulcers, also known as pressure sores, are difficult to treat medical problems that can lead to serious consequences. Pressure sores occur  
10 when the skin breaks down as a result of continuous pressure, thus forming open sores. Pressure sores frequently affect the skin over bony prominences of the body. Areas most commonly affected include the skin  
15 over the heel, ankle bones, coccyx or tailbone, trochanters or hip bones and the sacral area of the lower back.

An estimated 2 to 3 million people in the United States are affected by pressure sores, with most  
20 of them being elderly. One study showed that over 12% of nursing home residents developed pressure sores within their first year. This number increases to 20% after 2 years. Moreover, an estimated 60,000 people die from pressure sore complications every year.

Pressure sores occur when there is a lack of blood supply to a dependent area of the body. This lack of blood supply is caused by compression of the skin and underlying soft tissue between the bony  
5 prominence and a supporting surface, such as a mattress. The weight of the body part exerts sufficient pressure to impair the blood supply to the soft tissue and skin. If this impairment of the blood supply is prolonged, permanent injury results causing necrosis or  
10 death of the skin and underlying soft tissue in the affected area. Other factors causing pressure sores include friction of the skin against bed sheets, casts or braces.

Pressure sores commonly affect individuals  
15 with limited mobility, such as those confined to a bed because of illness, injury or old age. These are frequent problems in nursing home patients, especially those with circulatory problems, or impaired sensations because of diabetes or stroke.

20 Once a pressure sore occurs, treatment is very difficult and time consuming, often requiring weeks or months of wound care. Dressing changes are usually painful to the patient. Complications, including localized or generalized infection, may be  
25 serious and commonly require hospitalization for proper treatment. Surgical intervention is frequently required, including debridement or excision of dead tissue, skin grafting and even leg amputation.

Pressure sores are generally considered to be  
30 a preventable condition, but prevention has proven to be difficult, time consuming and costly. Prevention requires avoiding prolonged pressure on any area of the skin by frequently moving the patient, and attention to skin care is required to avoid irritation or chaffing.

35 Published patent application no. 2003/0032485

to Flam et al. discloses a number of skin protective devices for preventing pressure sores. In particular, the skin protective devices have an inner surface which conforms to the body part to be protected, and is made  
5 of a material suitable for distributing the weight of the body part over an extended area.

A bed pad comprising a plurality of air-filled cells for treating pressure sores is disclosed in U.S. Patent No. 5,462,519 to Carver. A skin  
10 protective device for ankles, heels and elbows is disclosed in U.S. Patent No. 5,944,683 to Baranowski. In Baranowski, the skin protective device is a cushion formed of a closed cell foam having a resilience with respect to pressure. The resilient cushioning foam may  
15 include air, gel or water.

Other skin protective devices such as air mattresses and floatation beds, foam, silicon gel, sponge rubber and sheepskin pads of various shapes have been available - but these are difficult to apply or  
20 maintain in position. Moreover, some are uncomfortable to the patient and some are prohibitively expensive.

In spite of these efforts, the incidence of pressure sores has not diminished. In fact, the problem is becoming more frequent as the population  
25 ages. More individuals require long-term care and are confined to nursing homes. As nursing homes become more short-staffed, caregivers have even less time to devote to frequently changing a patient's position, and to providing attention to skin care. There exists a  
30 need for a straightforward skin protective device that can be easily applied to a vulnerable area of the body, stays in position once applied, and does not cause discomfort.

**Summary of the Invention**

In view of the foregoing background, an object of the present invention is to reduce pressure damage to the skin of a person using a skin protective device that overcomes the above noted limitations.

This and other objects, advantages and features in accordance with the present invention are provided by a method comprising determining at least one location on the person susceptible to pressure damage, and adhesively securing a skin protective device to the at least one location. The skin protective device may comprise a substrate having an inner surface and an outer surface, an adhesive layer substantially covering the inner surface, and at least one fluid-filled cell on the outer surface. The fluid-filled cell advantageously increases the area over which the pressure is distributed, thereby reducing the effects of the pressure.

The adhesive layer may cover at least 75% of the inner surface of the substrate for adhesively securing the skin protective device to the skin of the person. The skin protective device is easily applied to the skin and is held in position via the adhesive layer without causing unnecessary discomfort to the person. The skin protective device may further comprise a removable protective layer on the adhesive layer, and the method may further comprise removing the protective layer before adhesively securing the skin protective device.

The at least one fluid-filled cell may comprise a single fluid-filled cell, or a plurality of fluid-filled cells in a side-by-side relation. Each fluid-filled cell may also define an exposed outermost surface for the skin protective device. The fluid-

filled cell may be filled with a gas, such as air, or a liquid or a gel.

The substrate may have a substantially uniform thickness throughout. In one embodiment, the substrate comprises a polymer, and the adhesive layer comprises hydrocolloid. The substrate may have either a flat shape or a predetermined arcuate shape. Also, the substrate may comprise a flexible material or a shape-retaining material.

10                    **Brief Description of the Drawings**

FIG. 1a is a side view of a skin protective device applied to the skin of a person in accordance with the present invention.

15                    FIG. 1b is a side view of the skin protective device illustrated in FIG. 1a before being applied to the skin of the person.

FIG. 1c is a side view of another embodiment of the skin protective device in accordance with the present invention;

20                    FIG. 2a is a side view of another embodiment of the skin protective device similar to that illustrated in FIGS. 1a and 1b but with a predetermined arcuate shape.

25                    FIG. 2b is a side view of another embodiment of the skin protective device similar to that illustrated in FIG. 1c but with a predetermined arcuate shape;

30                    FIG. 3a is a side view of a person's foot having yet another embodiment of a skin protective device with a single fluid-filled cell in accordance with the present invention applied to the heel.

FIG. 3b is a side view of a person's foot having still another embodiment of a skin protective device with a plurality of fluid-filled cells in

accordance with the present invention applied to the heel.

FIG. 4 is a side view of a person's foot with skin protective devices in accordance with the present invention applied to different locations susceptible to pressure damage.

#### **Detailed Description of the Preferred Embodiments**

The present invention will be described more fully hereinafter with reference to the accompanying drawings, in which preferred embodiments of the invention are shown. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art. Like numbers refer to like elements throughout, and prime and multiple prime notations are used to indicate similar elements in alternate embodiments.

A method for reducing pressure damage to the skin of a person in accordance with the present invention is based upon application of any of the various embodiments of a skin protective device illustrated in FIGS 1a-4. The method initially comprises determining at least one location 12 on the person susceptible to pressure damage, and adhesively securing a skin protective device 10 to that location, as illustrated in FIG. 1a.

A bedridden person, for example, has several locations on their body that are susceptible to skin irritations. These locations generally include an underlying bone structure having a bony prominence that concentrates the weight of the person over a small

region that increases the pressure at an interface between the bony prominence and the corresponding skin and soft tissue. The skin protective device 10 includes at least one fluid-filled cell 14 that advantageously  
5 increases the area over which the pressure is distributed, thereby reducing the effects of the pressure.

Referring now to FIG. 1b, the skin protective device 10 in accordance with the present invention will  
10 be discussed in greater detail. The illustrated skin protective device 10 includes a substrate 16 having an inner surface to be positioned adjacent the skin 12 of the person. An adhesive layer 18 substantially covers the inner surface of the substrate 16 for adhesively  
15 securing the skin protective device 10 to the skin 12. The skin protective device 10 is easily applied to the skin 12, and is held in position via the adhesive layer 18 without causing discomfort to the person. A removable layer 20 protects the adhesive layer 18 prior  
20 to application to the skin 12.

The adhesive layer 18 covers at least 75% of the inner surface of the substrate 16 so that it can advantageously hold the skin protective device 10 in position. The adhesive layer 18 may be similar to  
25 medical grade tape, for example. Moreover, the adhesive layer 16 may comprise a medicated dressing, such as a hydrocolloid or a hydrogel material.

The adhesive layer 18 is not limited to any particular pattern on the inner surface of the  
30 substrate 16. For example, the adhesive layer 18 may be formed as a solid or contiguous pattern, as readily appreciated by those skilled in the art. Alternately, the adhesive layer 18 may be in the form of spaced

apart strips or even intersecting strips. Other patterns are readily acceptable as long as the adhesive layer 18 covers at least 75% of the inner surface of the substrate 16.

5                   At least one fluid-filled cell 14 is on an outer surface of the substrate 16 to cushion the skin 12. The fluid-filled cell 14 may be a single cell as illustrated in FIGS. 1a and 1b, or a plurality of cells 14' in a side-by-side relation as illustrated in FIG. 10 1c. The fluid-filled cells 14, 14' respectively define an exposed outermost surface 14a, 14a' for the skin protective device 10, 10'. The exposed outermost surfaces 14a, 14a' of the fluid-filled cells 14, 14' contact the support surface resulting in pressure being 15 applied to the skin 12.

                  The fluid-filled cells 14a, 14a' are filled with either a gas or a liquid, as readily appreciated by those skilled in the art. The gas preferably includes air, whereas the liquid includes a water or 20 saline-based solution, for example. The fluid-filled cells 14a, 14a' may also be filled with a gel, as readily appreciated by those skilled in the art. The fluid-filled cells 14a, 14a' are preferably formed using a light-weight plastic material bonded to the 25 substrate 16, 16'. Of course, other types of materials suitable for retaining the gas or liquid may be used, as readily appreciated by those skilled in the art.

                  The fluid-filled cells 14a, 14a' are strong enough to withstand the pressure applied to it by the 30 weight of the part of the body to which the skin protective device 10, 10' is applied. The pressure in each of the fluid-filled cells 14a, 14a' is low enough to allow each cell to be deformable by the weight of the body part, but high enough to prevent the body part



from contacting the support surface. The size/volume of each fluid-filled cell 14a, 14a' depends on the size of the skin protective device 10, 10'. Larger skin protective devices 10, 10' have proportionally larger fluid-filled cells 14a, 14a'.

The illustrated substrate 16, 16' preferably has a uniform thickness, and is preferably made out of polymer, for example, or another compatible type material, as readily appreciated by those skilled in the art. The substrate 16, 16' may also be formed with a non-uniform thickness. In one embodiment, the substrate 16, 16' has a flat shape as illustrated in FIGS. 1a-1c. The flat shape is preferably suited for the flat surfaces of the body. In another embodiment, the substrate 16", 16'" has a predetermined arcuate shape as illustrated in FIGS. 2a and 2b. The predetermined arcuate shape allows the skin protective device 10", 10'" to conform to the parts of the body having a bony prominence.

The illustrated skin protective devices 10, 10', 10" and 10'" in accordance with the present invention can be made in different shapes and sizes to fit different parts of the body. The different parts of the body in which the skin protective devices 10, 10', 10" and 10'" can be applied include, for example, the toe, heel, ankle, trochanter, knee, sacrum, coccyx, buttocks, ischium, scapula, elbow and occiput.

Depending on the intended application, the substrate 16, 16', 16" and 16'" may comprise a flexible material or a shape-retaining material. A small skin protective device with a flexible substrate may be applied to the foot to prevent pressure sores from shoes, for example, as illustrated in FIG. 4. The size of such a skin protective device 10 would be small

enough to fit within the shoe when worn by the person. The fluid-filled cell 14 in this application is preferably a single cell.

Larger skin protective devices are preferred  
5 for the larger, flat surfaces of the body. Bony prominence areas such as the ankle, heel and elbow are preferably protected by a skin protective device 10", 10'" with a shape-retaining material, as best illustrated in FIGS. 3a and 3b. The illustrated shape  
10 is in the form of a cup to fit the body part, such as the heel.

Many modifications and other embodiments of the invention will come to the mind of one skilled in the art having the benefit of the teachings presented  
15 in the foregoing descriptions and the associated drawings. Therefore, it is to be understood that the invention is not to be limited to the specific embodiments disclosed, and that modifications and embodiments are intended to be included within the  
20 scope of the appended claims.